



**UNITED STATES DEPARTMENT OF COMMERCE
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HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/222,443 12/29/98 YANG H 17100

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HM12/1015

EXAMINER

CEPERLEY, M

ART UNIT

PAPER NUMBER

1641

4

DATE MAILED:

10/15/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/222,443

Applicant(s)
YANG et al

Examiner
Mary E. Ceperley

Group Art Unit
1641



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 21-23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 21-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, (1) as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and (2) as being based on a disclosure which is not enabling for the scope encompassed.

While the specification is enabling for the “chemical moiety” as defined by the structural formula in original claim 1, the specification does not reasonably provide enablement for the “assay reagent composition” and “system” of claims 21-23. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. There is no enabling description in the specification to establish definitions of the terms “an assay reagent composition”, “a chemical moiety”, “a system”, “a reagent mixture”, and “an agent”. Also, there is no generic description in

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the specification to define the required components of the "assay reagent composition" and "system".

4. Claims 21-23 are rejected under 35 USC 112, second paragraph, as being indefinite. It is unclear exactly what is meant by the following terms even when the claims are read in light of the specification: "an assay reagent composition", "a chemical moiety", "a system", "a reagent mixture", and "an agent".

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 21-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,858,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reagent of the instant claims has as its sole utility the method of the patent. The method and the

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“reagent” were not restricted during the prosecution of the parent applications (see the restriction requirement of July 24, 1996 in parent application S.N. 08/423,394). Further, the “assay reagent compositions” and “system” of the instant application are inclusive of the structure of the “chemical moiety” of claim 1 of the patent i.e. the claims of the instant application are broader than those of the patent.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

8. Claims 21-23 are rejected under 35 U.S.C. 102(b)/(e) as anticipated by each of Kankare (GB 2,217,007), Bard et al (U.S. 5,310,687), Kamin et al (U.S. 5,147,806), or Weber (U.S. 4,293,310).

Each of the references describes a set of reagents and their use which anticipate the “assay reagent composition” and “system” of the instant claims i.e. the reagents of the references have the same functions which are defined for the components of the “reagent compositions” and “system” of the instant claims. See Kankare: claim 1 wherein the “chemical moiety containing

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lanthanide” corresponds to the “chemical moiety” of (b) of instant claim 21 and see also page 8, B. Method wherein “the oxidizing compound” corresponds to the “agent” of (a) of instant claims 21 and 22; Bard et al: claim 1; Kamin et al: col. 6, lines 1-61 wherein the “TAG” corresponds to the “chemical moiety” of (b) of instant claims 21 and 22 and the “oxalate” corresponds to the “agent” of (a) of instant claims 21 and 22; Weber: col. 6, lines 38-56 wherein “ RuL_3 ” corresponds to the “chemical moiety” of (b) of instant claim 21 and “hydrazine” corresponds to the “agent” of (a) of instant claims 21 and 22.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


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Mary E. Ceperley
Primary Examiner
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